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| 10/566,350 | 01/27/2006 | Tetsuro Tateishi | KUZ0028USNP | 2515 |

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| EXAMINER |
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PURDY, KYLE A

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| ART UNIT | PAPER NUMBER |
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1611

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| NOTIFICATION DATE | DELIVERY MODE |
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04/10/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/566,350 | Applicant(s) TATEISHI ET AL. | |
| | Examiner Kyle Purdy | Art Unit 1611 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/27/2006, 10/22/2007 and 02/27/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 02/27/2008 wherein claims 1-20 are pending, claims 7 has been amended and claim 20 is newly added.
2. Claims 1-20 are presented for examination on the merits. The following rejections are made.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Modamio et al. (International Journal of Pharmaceutics, 1998, 173, 141-148; of record) in view of Hirano et al. (US 6495159; of record).**

5. Applicants are claiming an adhesive patch having a pressure-sensitive adhesive layer comprising bisoprolol wherein the composition of the pressure-sensitive adhesive layer contains an acrylic polymer obtained by copolymerizing a methacrylic ester with a methacrylic acid comprising a carboxyl group wherein the patch further comprises a backing contacting the pressure-sensitive adhesive layer.

6. Modiamo and Hirano are relied upon for disclosure described in the rejection of claim 1 under 35 U.S.C. 103(a) found on pages 3-6 in the office action mailed on 12/11/2007.

7. Modiamo fails to teach a patch which contains a backing layer contacting the pressure-sensitive adhesive layer.

8. The teaching of Hirano cures such a deficiency. Hirano teaches a patch (see abstract and Figure 1) that possesses a backing layer (i.e. drug permeable membrane) which is in direct contact with the pressure-sensitive adhesive layer.

9. It would have been obvious to one ordinarily skilled in the art, at the time the invention was made, to combine the teachings of Modiamo and Hirano with a reasonable expectation for success in arriving at a transdermal patch wherein the adhesive layer is contacting a backing layer. The significance of Modiamo is that it motivates using bisoprolol in a transdermal patch by disclosing that topical/transdermal delivery is a useful means for delivering pharmaceuticals like bisoprolol. Still however, Modiamo fails to teach a patch for delivering the drug. Hirano teaches a patch system for delivering a serotonin receptor antagonist. The patch of Hirano possess a backing layer directly attached to the adhesive layer. The claim would have been obvious to a person ordinarily skilled in the art because such a person has a good reason to pursue known options within his or her technical grasp. If such an undertaking leads to the inventions success, it is likely that the product is not one of innovation, but rather a product of ordinary skill and common sense. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Response to Applicants' Arguments

10. Applicants arguments filed 02/27/2008 regarding the rejection of claim 15 made by the Examiner under 35 USC 112, second paragraph have been fully considered and persuasive. This rejection is withdrawn.

11. Applicants arguments filed 02/27/2008 regarding the rejection of claim 1-9 and 11-19 made by the Examiner under 35 USC 103(a) have been fully considered but, respectfully are not found persuasive.

12. Applicants arguments filed 02/27/2008 regarding the rejection of claims 1-9 and 11-19 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 12/11/2007.

13. In regards to the 103(a) rejection encompassing claims 1-9 and 11-19, Applicant asserts the following:

A) Modiamo describes an *in vitro* permeation experiments and fails to teach a patch using bisoprolol;

B) Hirano fails to teach a drug as being present in the pressure sensitive adhesive layer;

C) Neither Higo nor Hirano specifically teach a patch using an acrylic polymer, and that the reference of Higo teaches away from using an acrylic polymer by reciting, "... SIS, PIB and blends of the two materials are most preferable"; and

D) The references are totally silent with regard to the patch being of controlled release.

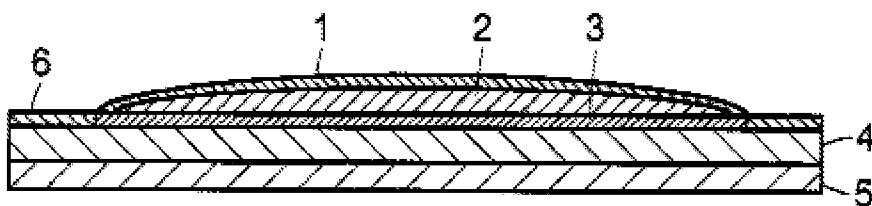
14. With respect to assertion A) from above, the fact that Modiamo is drawn to an *in vitro* experiment is considered moot because the study still addresses the issue of the penetration rate

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of bisoprolol across a section of human skin which, absent contrary results, would likely have the same properties *in vivo*. On that note, it is unclear why Applicant is arguing properties which are not present in the claims.

15. It is duly noted that Modiamo does not expressly disclose of a patch containing bisoprolol. Modiamo does however state that topical application of pharmaceuticals (such as bisoprolol) is useful for delivery of drugs with systemic activity. Such a recitation would necessarily motivate one of ordinary skill in the art to develop a means for delivering pharmaceutical agents across the skin via topical application of a transdermal patch. Moreover, as noted in the previous office action, Modiamo states that the transdermal pathway is of potential interest for the administration of drugs, which would again motivate one having ordinary skill to look to the art to identify a means for effectively administering pharmaceuticals such as bisoprolol across the skin in a safe and effective manner. The teaching of Modiamo would have led one of ordinary skill to combine the reference with that of Hirano and Higo to arrive at a patch with the instantly claimed properties.

16. With respect to assertion B) from above, Hiranos' invention would necessarily have to contain the drug in the adhesive layer. Applicant is directed to Figure 1 below:



Structure 2 is a drug containing pocket separated from the pressure sensitive adhesive layer 4 by a drug permeable membrane 3. It follows that as the medicine traverses the permeable

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membrane, it would necessarily be present in the adhesive layer. Applicants' argument is not found persuasive.

17. With respect to assertion C) from above, the fact that Higo states that "SIS and PIB are preferable" does not teach away from using other disclosed options. The term 'preferable' does not preclude someone from trying the other compounds listed that are disclosed to be useful for the very same purpose. Applicant also asserts that neither of Hirano or Higo specifically teaches a patch using an acrylic polymer. Applicant is mistaken. Hirano teaches a composition for a pressure-sensitive adhesive in Example 2 comprising 2-ethylhexyl acrylate/ethyl acrylate-vinyl acetate copolymer which is structurally similar to the acrylic polymer instantly claimed in claims 3, 4 and 15.

18. With respect to assertion D) from above, Applicant is arguing details that are not presently claimed.

Maintained Rejections
Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 1-9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modamio et al. (International Journal of Pharmaceutics, 1998, 173, 141-148; of record) in view of Hirano et al. (US 6495159; of record) and Higo et al. (US 5866157; of

record), further evidenced by Walters (Transdermal Drug Delivery, 1989, New York, NY, pp. 197-246).

21. The rejection of claims 1-9 and 11-19 under 35 USC 103(a) using the references above is maintained for the reasons of record set forth on pages 3-7 of the office action mailed on 12/11/2007.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
March 4, 2008*

*/Michael P Woodward/
Supervisory Patent Examiner, Art
Unit 1615*